

APPENDIX D – EVALUATION RESULTS CODES

Component/Subassembly Failures	
401	Absorber (CO2)
548	Accumulator
402	Actuator
431	Adapter
552	Air cleaner
549	Air pump assembly
403	Alarm
404	Alarm, assembly
405	Alarm, audible
407	Alarm, high inspiratory pressure
408	Alarm, LED
409	Alarm, low inspiratory pressure
410	Alarm, oxygen pressure
411	Alarm, power
412	Alarm, pressure
550	Alarm, self
413	Alarm, visual
414	Alarm, volume
590	Alternator
591	Altimeter
592	Amplifier
593	Analyzer
594	Annunciator
595	Antenna
596	Arrester
597	Attenuator
598	Backpanel
599	Backplane
417	Bacterial filter
730	Baffle
553	Bags
418	Ball
731	Ballast
419	Balloon
732	Barrier
420	Battery
733	Beam splitter
734	Bearings
735	Bell
737	Belt
738	Blower
739	Bobbin
740	Bolometer
741	Bolt
554	Bottom dead center sensor bracket
742	Brake
422	Breathing circuit
743	Brush
745	Bus

Component/Subassembly Failures	
746	Bushing
736	Buzzer
423	Cable
747	Calibrator
748	Camera
749	Cannula, inner
750	Cannula, outer
424	Cap
751	Capacitor
555	Capacitor (ceramic chip)
752	Carrier
556	Cascade
425	Cassette
753	Caster
754	Cell
426	Charger
755	Chassis
756	Choke
427	Circuit board
757	Clamp
758	Clip
759	Clock
428	CO2 monitor
429	CO2 monitor subassembly (only use when part of another device)
760	Coder
761	Coil
762	Collimator
763	Comparator
557	Compressor (air pump)
558	Concentrator
559	Conductor coil
560	Connecting rod
435	Connector
764	Contact lens
436	Control switches
765	Controller
766	Converter
767	Cooling module
768	Cord
769	Core
770	Counter
771	Coupler
772	Cover
437	CPU (central processing unit) board
561	Crank arm assembly
438	CRT (cathode ray tube)
773	Crystal
562	Cuff
563	Cup seal
774	Cups

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Component/Subassembly Failures	
775	Current limiter
776	Current source
439	Cusp
777	Cutter
440	Cylinder
441	Cylinder valve
778	Damper
779	Data acquisition unit
780	Decoder
442	Defibrillator paddles
443	Defibrillator subassembly (only use when part of another device)
781	Dehumidifier
782	Dehydrator
783	Delay line
784	Demagnetizer
785	Demodulator
786	Densitometer
787	Detector
788	Device deployer
789	Dial
445	Diaphragm
790	Digitizer
447	Diode
448	Discrete component/device (resistor, capacitor, diode)
791	Disk
416	Display
792	Divider
793	Dome
794	Doubler
795	Driver
796	Duct
797	Dummy load
798	Duplexer
450	EKG/ECG monitor
449	EKG/ECG subassembly (only use when part of another device)
452	Electrical lead
451	Electrode
799	Emitter
800	Enclosure
801	Encoder
802	Endoscope
454	EPROM (erasable programmable read only memory)
803	Equalizer
804	Evaporator
455	Exhalation filter
805	Expander

Component/Subassembly Failures	
806	Extender
807	Extractor
808	Eyelet
456	Fail-safe system
809	Fan
810	Fastener
811	Feedthru
812	Ferrule
813	FET (field effect transistor)
814	Fiber
815	Film
816	Filter
457	Flange
817	Flasher
458	Flowmeter
818	Foil
819	Foot pedal
459	Foot switch
820	Frame
460	Function indicator
564	Function lid
821	Furnace
822	Fuse
461	Gas scavenging
823	Gasket
462	Gauges/meters
824	Gear
565	Gears
825	Generator
826	Grille
827	Grommet
828	Ground strap
829	Guide
463	Guidewire
830	Handset
464	Header
831	Headphone
832	Heads
833	Headset
465	Heart valve cage
466	Heart valve leaflet
834	Heart valve sewing ring
835	Heat exchanger
836	Heat sink
467	Heater
566	Heater rod
567	Helifix coil
837	Hinge
838	Holder
468	Hollow fiber
839	Housing
469	Hub

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Component/Subassembly Failures	
470	Humidifier
471	Hybrid circuit
474	IC (integrated circuit)
472	IC (integrated circuit) chip
840	Igniter
841	Imager
842	Impedance converter
843	Indexer
844	Indicator
845	Inductor
473	Insulation
846	Integrator
847	Intercom
569	Interconnection board intubate
848	Interface
849	Interrupter
850	Inverter
851	IOL (intraocular lens) implant
852	Isolator
853	Jack
854	Joint
855	Joystick
856	Jumper
857	Junction
475	Keyboard
858	Keyer
859	Keypad
860	Kit
861	Knob
862	Label
863	Laminate
864	Lamp
865	Laser
476	Lead conductor
477	LED (light emitting diode)
866	Lenses
478	Limit switch
867	Limiter
868	Line conditioner
570	Line cord
479	Lithium iodide battery
869	Load
870	Lock
571	Locking sleeve
480	Logic board
572	Lower piston bearing
481	Luer valve
871	Magazine
482	Magnet
872	Magnetizer
873	Magnetometer

Component/Subassembly Failures	
874	Magnetoresistor
875	Magnifier
483	Manifold
876	Matrices
484	Membrane
877	Memory
878	Meter
573	Meter needle
879	Microcircuit
880	Microphone
881	Microscope
882	Mirror
883	Mixer
884	Modem
885	Modulator
886	Monitor
485	Mother board
486	Motor
574	Motor roll pin
887	Mount
888	Multiplier
889	Nebulizer (only use when part of another device)
890	Network
1023	None
891	Nuts
487	O2 monitor subassembly (only use when part of another device)
892	O2 sensor
488	Obturator
894	Optical cable
893	Optical disk
546	Optical fiber
895	Optocoupler
896	Oscillator
897	Oscilloscope
400	Other (code unspecified, describe in H10)
898	Outlet
899	Oven
575	Overlay
489	Oximeter
490	Oximeter (only use when part of another device)
491	Oxygen analyzer
900	Pad
901	Panel
492	PC (printed circuit) board
902	Photodetector
903	Photomultiplier
904	Phototransistor
905	Pickup

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Component/Subassembly Failures	
493	Pilot balloon valve
906	Pin
576	Piston guides
577	Piston heads
578	Piston Pads
494	Pivot
907	Plate
908	Plotter
579	Plug
910	Pointer
911	Polarizer
495	Port
912	Post
496	Potentiometer
497	Power cord
580	Power lamp
913	Power module
498	Power supply
499	Power switch
914	Preamplifier
915	Prescaler
916	Preselector
500	Pressure sensor
581	Pressure signal
501	Pressure tubing
917	Printer
918	Probe
919	Processor
920	Programmer
503	PROM (programmable read only memory)
504	Prong
921	Protector
922	Proximity switch
923	Pulley
924	Pulser
925	Pump
926	Pyrometer
927	Rail
505	RAM (random access memory)
928	Reactor
929	Reader
930	Receiver
507	Recorder (tape, stripchart, etc.)
931	Rectifier
582	Reed (electrically open)
932	Regulator
508	Relay
933	Repeater
934	Reservoir
935	Resistor

Component/Subassembly Failures	
936	Resolver
937	Resonator
938	Retainer
583	Retaining pin
939	Reticle
940	RFI (radio-frequency interference)
941	Rheostat
942	Ribbon
943	Ring
944	Rivet
945	Robot
946	Rod
509	ROM (read only memory)
947	Safety interlock
984	SAW (surface acoustic wave device)
949	Scale
948	Scaler
950	Scanner
951	Scintillometer
952	Scrambler
953	Screen
568	Screw
954	Scriber
432	Seal
584	Seal tracheal
510	Sensor
551	Servo
955	Shaft
956	Shield
957	Shift register
958	Shifter
959	Shunt
960	Shutter
961	Signal conditioner
962	Simulator
963	Slide
964	Slip ring
965	Slotter line
967	Socket
966	Socket adaptor
511	Solder joint
512	Solenoid
968	Sound absorber
969	Spacer
970	Spark gap
971	Speaker
972	Spectrometer
514	Spirometer
973	Splicer
974	Spooler
975	Spring

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Component/Subassembly Failures	
976	Stabilizer
977	Stand
515	Stent
516	Stepper motor
978	Stiffener
517	Stopcock
979	Strain relief
980	Strip line
518	Stylet
981	Substrate
982	Sunlamp
983	Suppressor
519	Switches
985	Synchronizer
986	Synthesizer
987	Syringe
988	Table
989	Tachometer
990	Tape
991	Tee
520	Telemetry equipment
992	Telephone
1019	Washer
1020	Waveguide
1021	Window
430	Wire
993	Teleprinter
994	Teletypewriter
995	Television unit
996	Temperature compensator
997	Terminal
585	Terminal assembly
998	Terminator
999	Thermistor
1000	Thermocouple
547	Thermocouple wire
1001	Thermometer
1002	Thermostat
1003	Thyristor
1004	Timer
586	Tip conductor coil
1005	Trackball
1006	Transceiver
522	Transducer
523	Transformer
524	Transistor
1007	Translator
1008	Transmission line
1009	Transmitter
1010	Transponder
1011	Transport
1012	TRIAC

Component/Subassembly Failures	
1013	Trimmer
525	Tube
587	Tube capillary
1014	Tuner
444	User interface
527	Valve
528	Valve (one-way, hemo, stopcock, etc.)
529	Valve, control
530	Valve, directional
589	Valve, dump
531	Valve, exhalation
532	Valve, flap
533	Valve, flow
534	Valve, inhalation
535	Valve, inlet port
536	Valve, inspiratory
537	Valve, outlet port
538	Valve, PEEP (positive end expiratory pressure)
539	Valve, pressure limit
540	Valve, relief
541	Valve, safety
542	Valve, selector
543	Vaporizer
1015	Varistor
588	VDT (video display terminal)
1016	Vibrator
1017	Viewer
1018	Voltmeter
544	Wiring harness
545	Y-piece connector
1022	Yoke

APPENDIX D – EVALUATION RESULTS CODES

Computer-, Imaging System-, Microprocessor-Controlled Device Problems	
617	Algorithm analysis
618	Algorithm problem
657	Bus conflicts
633	Bus corruption
653	Cache controller
652	Cache memory
635	Calculation error (pentium)
601	Central processing unit/operating system - error/design
643	Cold
628	Communication
663	Compression errors
603	Computer - user interface
602	Computer hardware problem
605	Computer software problem
616	Computer software problem - error/design
658	Conducted interference
626	Data corruption
631	Deadlock
647	Dirt
655	DMA controller (direct memory access)
646	Dust
664	Electromagnetic interference
648	Electrostatic discharge
630	Glitch
642	Heat
645	Humidity
656	I/O (input/output) controller
627	I/O (input/output) integrity
637	Interrupt errors
621	Kernel
638	Latch-up
644	Liquid ingress
606	Magnetic interference
607	Medical diagnosis software
654	Memory access errors
629	Metastable state
608	Modem/communications failure
665	None
600	Other (code unspecified, describe in H10)
609	Poor image resolution
659	Power fluctuation
610	Power loss/surge related

Computer-, Imaging System-, Microprocessor-Controlled Device Problems	
	complication
662	Power sequencing
661	Power spike
660	Power transient
640	Power-up errors
641	Radiation effects
622	Real-time operating system
639	Reset errors
611	RF interference
612	Safety interlock/feature failure
625	Sequence processing
650	Shock
636	Stack errors
619	State machine
651	Temperature fluctuation
634	Timing violation
620	Token
632	Transmission effects
613	User installation error
614	User maintenance error
624	Vector processing
649	Vibration
623	Watchdog

RESULTS OF EVALUATION CODES DEVICE	
703	Alarms inadequate or absent
101	Component/subassembly failure (select specific code from Category D)
103	Computer hardware problem
104	Computer software problem
105	Computer/human interface problem
705	Controls, switches, keypads difficult to read or use
704	Critical information not displayed
110	Design (unspecified)
115	Design - maintenance difficult
112	Design - not fail safe
114	Design - operational context
111	Design - packaging deficiencies
113	Design - user interface
706	Device difficult to assemble or set up
708	Device performed according to specifications
702	Display hard to read or misleading
120	Electrical problem (unspecified)
122	Electrical problem - open circuit
123	Electrical problem - operating outside specifications
121	Electrical problem - short circuit
197	Electro-magnetic interference problem
198	Electro-static interference
133	End of life - expected
134	End of life - premature
138	Exceeded expected life of device
140	Expected wear/deterioration
141	Failure to cycle
142	Foreign material contamination
196	Inadequate optical transmission
143	Inadequate quality assurance/control
102	Incompatible components

RESULTS OF EVALUATION CODES DEVICE	
168	Instructions not available
144	Insulation degradation/deterioration
154	Labeling contains inadequate instructions for use/maintenance
157	Labeling contains incorrect instructions for use/maintenance
151	Labeling difficult to read/see
152	Labeling difficult to understand
153	Labeling does not provide necessary information
156	Labeling is incomplete
159	Labeling is not available
150	Labeling problems (unspecified)
145	Lubrication excessive
146	Lubrication insufficient
147	Lubrication, loss of
148	Lubrication, wrong SAE (specifications)
149	Lubrication, wrong type used - oil vs grease
170	Manufacturing
174	Manufacturing - materials
171	Manufacturing - packaging
172	Manufacturing - process
173	Manufacturing - quality control
175	Manufacturing - user interface
135	Material degradation/deterioration, anticipated or expected
137	Material degradation/deterioration, unanticipated or unexpected
136	Material problem - post production
180	Mechanical problem (i.e. pump, motor, wiring, cable, battery, parts, friction, etc.)
710	Negative results of device testing
709	None
707	Operating steps confusing
100	Other (code unspecified, describe in H10)
190	Out of specification
160	Package insert information

RESULTS OF EVALUATION CODES DEVICE	
	inadequate/incorrect
167	Package insert missing
162	Package labeling inadequate/incorrect
163	Package mislabeled
131	Premature power source depletion
132	Premature RRT indicator (recommended replacement time)
191	Quality assurance
164	Service manual (use in conjunction with another labeling code)
192	Shelf life exceeded
195	Sterilization
193	Storage/shipment
194	Telemetry failure
176	Tolerance stack-up (hardware/software)
165	User instruction manual (use in conjunction with another labeling code)
701	User/device interface

USE OF DEVICE	
201	Cleaning error
213	Device used according to labeled indications
214	Device used in appropriate environment
202	Device used with inappropriate material
215	Device used with incompatible equipment
203	Device used with incompatible medium/material
204	Disinfection error
205	Failure to follow instructions
206	Failure to remove packaging per use instructions
207	Failure to service/maintain according to manufacturer recommendations
208	Incorrect technique/procedure
209	Misapplication/misuse of device
223	Modification of device - by authorized service organization
225	Modification of device - by distributor
224	Modification of device - by other service organization
221	Modification of device - by user/user facility biomedical engineering department
220	Modification of device - unspecified
236	Negative results of device testing
235	None
200	Other (code unspecified, describe in H10)
230	Reuse of device - unspecified
232	Reuse of device beyond labeled specifications
708	Device performed according to specifications
702	Display hard to read or misleading
120	Electrical problem (unspecified)
122	Electrical problem - open

USE OF DEVICE	
	circuit
123	Electrical problem - operating outside specifications
121	Electrical problem - short circuit
197	Electro-magnetic interference problem
198	Electro-static interference
133	End of life - expected
134	End of life - premature
138	Exceeded expected life of device
140	Expected wear/deterioration
141	Failure to cycle
142	Foreign material contamination
196	Inadequate optical transmission
143	Inadequate quality assurance/control
102	Incompatible components
168	Instructions not available
144	Insulation degradation/deterioration
154	Labeling contains inadequate instructions for use/maintenance
157	Labeling contains incorrect instructions for use/maintenance
151	Labeling difficult to read/see
152	Labeling difficult to understand
153	Labeling does not provide necessary information
156	Labeling is incomplete
159	Labeling is not available
150	Labeling problems (unspecified)
145	Lubrication excessive
146	Lubrication insufficient
147	Lubrication, loss of
148	Lubrication, wrong SAE (specifications)
149	Lubrication, wrong type used - oil vs grease
170	Manufacturing
174	Manufacturing - materials
171	Manufacturing - packaging
172	Manufacturing - process
173	Manufacturing - quality

USE OF DEVICE	
	control
175	Manufacturing - user interface
135	Material degradation/deterioration, anticipated or expected
137	Material degradation/deterioration, unanticipated or unexpected
136	Material problem - post production
180	Mechanical problem (i.e. pump, motor, wiring, cable, battery, parts, friction, etc.)
710	Negative results of device testing
709	None
707	Operating steps confusing
100	Other (code unspecified, describe in H10)
190	Out of specification
160	Package insert information inadequate/incorrect
167	Package insert missing
162	Package labeling inadequate/incorrect
163	Package mislabeled
131	Premature power source depletion
132	Premature RRT indicator (recommended replacement time)
191	Quality assurance
164	Service manual (use in conjunction with another labeling code)
192	Shelf life exceeded
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202	Device used with inappropriate material
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203	Device used with incompatible medium/material
204	Disinfection error
205	Failure to follow instructions
206	Failure to remove packaging per use instructions
207	Failure to service/maintain according to manufacturer recommendations
208	Incorrect technique/procedure
209	Misapplication/misuse of device
223	Modification of device - by authorized service organization
225	Modification of device - by distributor
224	Modification of device - by other service organization
221	Modification of device - by user/user facility biomedical engineering department
220	Modification of device - unspecified
236	Negative results of device testing
235	None
200	Other (code unspecified, describe in H10)
230	Reuse of device - unspecified
232	Reuse of device beyond labeled specifications
234	Reuse of device without following disinfection/sterilization instructions
231	Reuse of disposable device
233	Reuse of single use device
211	Timing error
212	Unapproved use of device

PHYSIOLOGICAL / PROCEDURAL FACTORS	
311	Anticipated adverse reaction - long term
312	Anticipated adverse reaction - short term
310	Anticipated or known (physiological/ procedural related, but code unspecified)
321	Caused by another drug/device
323	Caused by magnetic field - MRI
324	Caused by metal - microwave
325	Caused by operational context
331	Environmental factors
332	High/low temperature or humidity
313	Inherent risk of procedure
314	Known long term complication of procedure
315	Known short term complication of procedure
346	Negative results of device testing
345	None
300	Other (code unspecified, describe in H10)
333	Patient diagnosis contraindicated use of device
316	Patient's condition - predisposed event
317	Patient's condition affected effectiveness of device
318	Patient's condition contraindicated use of device
322	Related to another drug/device
326	Related to operational context
334	Support system problem (e.g., facility oxygen flow system, electrical Failure of entire facility)
340	Unanticipated (physiological / procedural related, but code unspecified)
341	Unanticipated adverse

	reaction - long term
342	Unanticipated adverse reaction - short term
343	Unanticipated long term complication of procedure
344	Unanticipated short term complication of procedure